

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE)
COMPANY, INC.,)
Plaintiff,)
vs.) Case No.
INTUITIVE SURGICAL, INC.,)
Defendant.)

VIRTUAL VIDEOCONFERENCE VIDEO-RECORDED
DEPOSITION OF GREG POSDAL
(B)(6), SURGICAL INSTRUMENT SERVICE COMPANY

Tuesday, November 1, 2022

Stenographically Reported By:
Hanna Kim, CLR, CSR No. 13083
Job No. 5541334-A

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SURGICAL INSTRUMENT SERVICE)
COMPANY, INC.,)
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=====)

Virtual videoconference video-recorded deposition of GREG POSDAL, in the capacity of a 30(B)(6) witness of Surgical Instrument Service Company, Remotely Testifying from Phoenix, Arizona, on Tuesday, November 1, 2022, beginning at 9:01 a.m., PDT, and concluding at 10:52 a.m., pursuant to the stipulations of counsel thereof, before Hanna Kim, CLR, Certified Shorthand Reporter, No. 13083.

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1 sterile processing, there's another set of eyes on
2 it to make sure that it appears to be safe for work.
3 At that time, they're pulled out.

4 With the Intuitive instruments, there's a
5 forced inspection at ten. And we were willing to 09:48:01
6 abide by that same inspection process.

7 Q. Do you believe there would have been a
8 regulatory issue with adding 19 lives to an
9 instrument as opposed to just adding ten?

10 MR. SNYDER: Objection to form. 09:48:24

11 THE WITNESS: No.

12 BY MR. CHAPUT:

13 Q. Why not?

14 A. Well, Intuitive's own 510(k) submission
15 called this item substantially equivalent to 09:48:40
16 predicate devices, and those are the devices that
17 we've repaired for decades.

18 Q. Why does that mean that there's no
19 regulatory issue with adding 19 lives to an
20 instrument as opposed to the ten that it's initially 09:49:01
21 set for?

22 A. There are --

23 MR. SNYDER: Objection to form.

24 THE WITNESS: There are no regulations for
25 that. The FDA stayed out of repair. They don't -- 09:49:09

1 we've had -- it has not been a necessity to deal
2 with any regulatory issues with re- -- regarding the
3 repair of surgical instrumentation.

4 BY MR. CHAPUT:

5 Q. So I -- I think implicit in what you just 09:49:25
6 said is that SIS has determined that its reset
7 process is a repair; is that correct?

8 MR. McCARLLEY: Objection to form.

9 THE WITNESS: The -- the reset process
10 is -- we've used repair as kind of an umbrella term. 09:49:39
11 That could be resetting the chip, could be repairing
12 an instrument. So I don't -- I don't know if that
13 answers your question specifically. But simply
14 evaluating the instrument and resetting the chip
15 wouldn't technically be a repair. No repair was 09:50:03
16 done. The chip was reset. So it would depend on
17 the condition and what services were performed.

18 BY MR. CHAPUT:

19 Q. Okay. I'm just -- I'm just trying to
20 reconcile these questions because initially you said 09:50:27
21 there's -- there's no problem because the FDA has
22 stayed out of repair, but you also just said that if
23 there's a chip reset without anything else done,
24 that that doesn't count as repair. So I -- I'm --
25 what I'm trying to understand is, how did SIS come 09:50:44